Translation

PATENT COOPERATION TREATY

PCT

PCT Application
PCT/CN2002/000661

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
024618PC		
International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/CN02/00660	16 September 2002 (16.09.2002)	28 August 2002 (28.08.2002)

International Patent Classification (IPC) or national classification and IPC

IPC[7] : A61K38/04, A61K38/19, C07K7/08, A61P37/00

Applicant

SHANGHAI YIZHONG BIOTECHNOLOGY CO., LTD et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26 March 2004 (26.03.2004)	28 December 2004 (28.12.04)
Name and mailing address of the IPEA/	Authorized officer
	CHANG, mao
Facsimile No.	Telephone No. 86-10-62085298

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/CN02/00660

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

☐ the claims:

pages _____ as originally filed/furnished

pages * _____ as amended (together with any statement)under Article 19

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/CN/02/00660

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement:

Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims	1-10	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Novelty:

Claims 1-10 of the present invention disclosed a pharmaceutical composition that mainly comprising Osteogenic Growth Peptide (OGP) and Granulocyte Colony Stimulating Factor (G-CSF). Although OGP and G-CSF are disclosed separately in the prior art, there has not been found the combination of using the two together, so Claims 1-10 meet the requirements of PCT Article 33(2).

Inventive steps:

The present invention disclosed that while the OGP and G-CSF are using together in the reasonable ratio range, a good synergism has been realized in promoting the haematogenesis of G-CSF. There is no hint for using the two together from the prior art, and it is not obvious for a skilled person to find the ratio range between OGP and G-CSF. Thus Claims 1-10 meet the requirements of PCT Article 33(3).

Utility:

The composition that comprising OGP and G-CSF could be used to promote the Haematogenesis, so the composition could be used in pharmaceutical field, thus claims 1-10 meet the requirements of PCT Article 33(4).

专 利 合 作 条 约

PCT

专利性国际初步报告

（PCT 第II章）

（PCT 36 和细则 70）

申请人或代理人的档案号 024618PC	关于后续行为 参见 PCT/IPEA/416 表	
国际申请号 PCT/CN02/00660	国际申请日（日/月/年） 16.9 月 2002 (16.09.2002)	优先权日（日/月/年） 28.8 月 2002 (28.08.2002)
国际专利分类(IPC)或者国家分类和 IPC 两种分类 IPC[7] : A61K38/04, A61K38/19, C07K7/08, A61P37/00		
申请人 上海益众生物技术有限公司 等		

1. 本报告是国际初步审查单位根据条约 35 做出的国际初步审查报告，并依照条约 36 将其传送给申请人。

2. 本报告共计 3 页，包括扉页。

3. ☐ 本报告还有附件，

   a. ☐ （传送给国际局和申请人)共计 _____页，包含

   ☐修改后的并且作为本报告基础的说明书修改页、权利要求书修改页和/或附图修改页，和/或对本国际初步审查单位所做出的更正页(见 PCT 细则 70.16 和行政规程 607)。

   ☐国际初步审查单位认为修改超出原始公开范围的废除页，参见第 I 栏第 4 项和补充栏。

   b. ☐ （传送给国际局）共计 (指明电子载体的类型和数量) _____，包含有在与序列表有关的补充栏中指明的计算机可读形式的序列表和/或与其相关的表格。（行政规程 802）

3. 本报告包括关于下列各项的内容：

- I ☒ 报告的基础
- II ☐ 优先权
- III ☐ 不做出关于新颖性、创造性和工业实用性的意见
- IV ☐ 缺乏发明的单一性
- V ☒ 按条约 35(2)关于新颖性、创造性或工业实用性的推断性意见；支持这种意见的引证和解释
- VI ☐ 引用的某些文件
- VII ☐ 国际申请中的某些缺陷
- VIII ☐ 对国际申请的某些意见

提交要求书的日期 26.3 月 2004 (26.03.2004)	完成本报告的日期 28.12 月 2004 (28.12.2004)
中华人民共和国国际知识产权局 IPEA/CN 中国北京市海淀区西土城路 6 号(100088) 传真号：(86-10)62019451	受权官员 常 矛 印 电话号码 (86-10)62085298

专[redacted]国际初步报告

国[redacted]申请号 PCT/CN02/00660

I. 报告的基础

1. 关于所使用的语言，除本项下另有说明外，本书面意见基于的语言为提交本国际申请时所使用的语言。

☐本书面意见基于原始语言的使用后述语言之译文 _____，

这种语言是

☐ 为了国际检索而提交的译文所使用的语言（细则 12.3 和 23.1（b））。

☐ 为了国际申请的公布而提交的译文所使用的语言（细则 12.4）。

☐ 为了国际初步审查而提交的译文所使用的语言（细则55.2和/或55.3）。

2. 关于国际申请中各个部分，本报告基于（申请人为答复受理局根据条约 14 所发通知而提交的替换页，在本报告中视为“原始提交”的文件，不作为本报告的附件）

☒ 原始提交的国际申请。

☐ 说明书， 第 _____ 页 原始提交的，

第 _____ 页 _____ 初审单位收到的，

第 _____ 页 _____ 初审单位收到的。

☐ 权利要求， 第 _____ 页， 原始提交的，

第 _____ 页， 按条约 19 条修改的(附有说明)，

第 _____ 页 _____ 初审单位收到的，

第 _____ 页 _____ 初审单位收到的。

☐ 附图， 第 _____ 页，原始提交的。

第 _____ 页*， _____ 初审单位收到的，

第 _____ 页*， _____ 初审单位收到的。

☐ 序列表和/或相关表格——参见与序列表有关的补充栏。

3. 修改导致以下内容的删除：

☐ 说明书， 第 _____ 页

☐ 权利要求， 第 _____ _____ 项

☐ 附图， 第 _____ 页， 图 _____

☐ 序列表（*具体说明*） _____

☐ 与序列表相关的表格（*具体说明*） _____

4. ☐ 由于本报告附件的(某些)修改，如下所列，被认为超出了原始公开的范围，如补充栏所示，因此本报告是按照没有修改的情况做出的(细则 70.2(c))。

☐ 说明书， 第 _____ 页

☐ 权利要求， 第 _____ 项

☐ 附图， 第 _____ 页，图 _____

☐ 序列表（具体说明） _____

☐ 与序列表相关的表格（具体说明） _____

*如果第 4 项适用，一些或全部的文件页可能做出“废除”标记。

V. 按条约35 (2)关于新颖性、创造性或工业实用性的推断性意见；支持这种意见的引证和解释

1. 意见

新颖性(N)	权利要求	1-10	是
	权利要求		否
创造性(IS)	权利要求	1-10	是
	权利要求		否
工业实用性(IA)	权利要求	1-10	是
	权利要求		否

2. 引证和解释（细则 70.7）

关于新颖性：

本申请权利要求 1—10 涉及将主要含有成骨生长肽和粒细胞集落刺激因子制备成药物组合物。虽然成骨生长肽和粒细胞集落刺激因子已经是现有技术，但是在现有技术中没有发现将两者一起使用的技术方案，因此本申请权利要求 1-10 符合 PCT 第 33(2)条关于新颖性的规定：

关于创造性：

本申请公开了将成骨生长肽和粒细胞集落因子按照一定的比例混合使用的时候，产生了协同作用，现有技术中没有将成骨生长肽和粒细胞集落因子联合使用的提示，发现成骨生长肽和粒细胞集落因子能够按一定的比例混合后产生协同效果这一点，对于本领域技术人员来说也不是显而易见的，因此权利要求 1-10 要求保护的内容符合 PCT 第 33(3)条关于创造性的规定。

关于实用性：

权利要求 1-10 要求保护的由骨生长肽和粒细胞集落因子按照一定的比例混合而制备的药物组合物可以用于促进造血，因此，所述药物可以用于医药领域，所以权利要求 1-10 符合 PCT 第 33(4)条关于实用性的规定。